REMARKS

Claim 21 has been amended only by introducing the limitations of claim 17 to place it into independent form. No other amendments are proposed.

Finality of the Rejection.

It is unclear to applicants why the amendment to the claims necessitated any new ground for rejection. Prior claim 1 is substantially the same as proposed claim 21 except that claim 21 is limited to 2S albumin. 2S albumin was already in the claims in dependent claim 4, and specifically Brazil nut 2S albumin as specified in claim 22 was in dependent claim 6 as previously pending. Therefore, claim 21 is essentially of the same scope as former claim 4 except limited to 2S protein without an alternative. That said, the rationale for the prior rejection focused on the 2S albumin and this was taken into account in interpreting WO02/074250 (Panacea) and thus it is difficult to see how the amendment necessitated the presently outstanding rejection. Applicants are gratified that perhaps the arguments made in the previous Response resulted in the change from anticipation by Panacea to obviousness over Panacea in combination with Bartolomé, but the amendment to the claims does not appear to have done so. Withdrawal of finality of the present rejection is therefore respectfully requested.

Non-Elected Invention

It is unclear to applicants why claims 17-20 are said to represent a non-elected invention. The Office action mailed 28 December 2009 said explicitly that the application was enabling for "a method of decreasing allergenicity of 2S albumin Ber e 1 from Brazil nuts by alkylating and reducing the protein." Therefore, it appears that the Office contemplated such a claim. Further,

there was no restriction requirement with respect to claims of the subject matter of claims 17-20 since those claims did not originally appear in that form. But these claims raise only the same issues as claims 21-22 since they require that the allergenicity of the 2S albumin be decreased by means of the method. Thus, they are different from prior non-elected claims 14-15 which simply required a reduced and alkylated composition (as opposed to a method to decrease allergenicity).

Withdrawn Rejection

Applicants are grateful that the rejection under 35 U.S.C. § 112, paragraph 1, has been withdrawn.

The Outstanding Rejection

Claims 21-22 were rejected as assertedly obvious over WO02/074250 (Panacea) in view of Bartolomé, B., *et al., Allergol. Immunopathol.* (1997) 25:135-144 (Bartolomé).

The Office is of the view that Panacea teaches a method for treating an individual suffering from food allergy by administering a therapeutically effective amount of an allergen modified by reduction and alkylation wherein the allergen is Brazil nut 2S albumin. Respectfully, this is not an accurate statement of the teaching of Panacea. If it were, Panacea would destroy novelty of claims 21 and 22. Panacea at the cited sections on pages 3-4 and the section immediately prior thereto discusses getting rid of IgE binding sites which are putatively responsible for the allergenicity "by altering as little as a single amino acid within a protein…" or alternatively "disrupting one or more of the disulfide bonds that are present in the natural allergen." Reduction and alkylation is thus considered one possible option. The discussion in the cited section is completely generic and any application to a 2S albumin is based on the inclusion of 2S albumin in an extensive list of multiple allergens that occupies 15 pages of tables.

As pointed out in the previous Response, as the Examiner kindly recognizes, when a 2S albumin is illustrated in Panacea, it is modified by mutation not by reduction and alkylation. Therefore, a more accurate description of Panacea is that it teaches that one method to reduce allergenicity may be to reduce and alkylate the allergen or as an alternative to mutate an amino acid and also that 2S albumin is a known allergen.

Applicants appreciate that apparently the Office recognizes that this is the case since Bartolomé is required to support the rejection. Bartolomé concerns identifying the allergens from Brazil nut and concludes that 2S albumin is one of them. The Office states that Bartolomé teaches that the particular 2S albumin of Brazil nut is resistant to proteolytic digestion and can pass through the mucosal membrane without proteolytic degradation or denaturation thus conferring allergic properties. Bartolomé does say this, but the data obtained by Bartolomé contradict any conclusion that reduction and alkylation of 2S albumin would result in lack of allergenicity, and Bartolomé does not suggest that it would.

On the contrary. As noted by the Examiner, Panacea teaches that it is IgE binding properties that are responsible for allergenicity. Bartolomé teaches on page 142, left-hand column, that

> Immunoblotting assays in tricine SDS-PAGE under reducing conditions revealed the IgE binding capacity of both the large (9 kD) and small (3 kD) 2S albumin subunits.

Thus, rather than suggesting that this method would be successful in overcoming allergenicity, Bartolomé specifically teaches that it would not. The subunits liberated by the reduction and alkylation are still allergenic in that they bind IgE.

Thus, Bartolomé fails to make up for the deficiencies of Panacea, and this basis for rejection may be properly withdrawn.

Conclusion

The claims have been amended to place claim 21 in independent form, and it has been argued that effectively claims 17-20 represent the same invention as the Office apparently recognized in the previous Office action. Further, applicants have argued that finality should be withdrawn since the amendment to the claims did not alter the nature of the issues, but only focused on dependent claims that were already made the basis for the rejection in the previous Office action.

Nevertheless, the current outstanding rejection over the combination of Panacea and Bartolomé should be withdrawn as Bartolomé teaches that the subunits of 2S albumin which would be formed by reduction and alkylation remain able to bind IgE and thus would be expected to be allergenic. This expectation was disproved by the examples in the present application.

Applicants respectfully request that claims 17-22 be passed to issue.

Should minor issues remain that might be resolved over the phone, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 677132000200.

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Respectfully submitted,

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